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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,852	12/10/2003	Frederick L. Hall	06666-042002 / 2895	4628

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EXAMINER	
DEBERRY, REGINA M	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,852	HALL ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 10 December 2003 has been entered in full. Claims 1-65 are cancelled. New claims 66-80 are added. Claims 66-80 are under examination.

Information Disclosure Statement

The information disclosure statement(s)(IDS) filed 10 December 2003 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 66-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Hall et al., US Patent 6,387,663 B1.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this

application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Hall et al. teach a fusion polypeptide comprising a collagen-binding domain of von Willebrand factor and an epidermal growth factor (EGF) domain (claims 1-4). Hall et al. teach a pharmaceutical composition including a fusion polypeptide containing a collagen binding linking to an angiogenesis modulating agent in a pharmaceutically acceptable carrier (column 4, lines 12-20). Hall et al. teach EGF as an angiogenesis modulating agent (column 7, lines 1-5).

Claims 72-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Hall et al., US Patent 6,955,898 B2.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Hall et al. teach a nucleic acid sequence encoding a fusion polypeptide comprising a collagen-binding domain and an epithelial cell proliferation-modulation domain. Hall et al. teach a retroviral vector, a promoter, a method of producing the fusion polypeptide, prokaryotic and eukaryotic host cells (claims 1-25).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 66, 67, 70, 72-74, 76-78 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall *et al.,* WO 96/39430 (reference submitted by Applicant).

Hall *et al.* teach a fusion polypeptide comprising transforming growth factor beta domain and a collagen binding domain (TGFβ-F2)(abstract; page 2, lines 30-32; page 4, line 27-page 5, line 5)(**applies to claims 66, 67, 70**). Hall *et al.* teach methods of preparation of the fusion protein (page 2, line 26-page 3, line 5). Hall *et al.* teach the recombinant expression of TGFβ fusion protein in *E. coli* and purification (pages 10-12 and pages 15-17)(**applies to claims 72-74, 76-78**). Hall *et al.* teach pharmaceutical compositions comprising TGFβ/collagen binding domain fusion protein (page 8, lines 15-20 and page 30)(**applies to claim 80**).

Claims 66, 67, 70-74, 76-78 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishi *et al.,* Proc. Natl. Acad. Sci. USA, Vol. 95:7018-7023 (1998)(reference submitted by Applicant). Nishi *et al.* teach a fusion protein comprising EGF and a collagen binding domain (EGF/CB) (abstract; page 7018, 4th paragraph; page 7019 and page 7020, 1st paragraph)(**applies to claims 66, 67, 70, 71**). Nishi *et al.* teach the recombinant expression of fusion protein EGF/CB in *E. coli* and purification (page 7019, Material and Methods, 1st-2nd paragraph and Figure 1)(**applies to claims 72-74, 76-78**). Nishi *et al.* teach the administration of EGF/CB and PBS into rats (page 7019, *In Vivo* Studies, 5th paragraphs)(**applies to claim 80**).

Claims 66-69, 71-74, 76-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon *et al.,* Human Gene Therapy Vol. 8:1385-1394 (1997)(reference submitted by Applicant). Gordon *et al.* teach a fusion protein comprising a collagen-binding domain {von Willebrand Factor (vWF)} and an epithelial cell proliferation-modulation domain (TGF-β1)(page 1386, 1st paragraph)(**applies to claims 66-68, 71**). Gordon *et al.* teach the decapeptide sequence of vWF (page 1386, Figure 1) (**applies to claim 69**). Gordon *et al.* teach the recombinant expression of fusion protein TGF-β1/vWF in *E. coli* and purification (page 1386, Material and Methods, 2nd paragraph and Figure 1)(**applies to claims 72-74, 76-78**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 75 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Gordon *et al.,* Human Gene Therapy Vol. 8:1385-1394 (1997) in view of Temin *et al.,* US Patent No. 4,980,289. The teachings of Gordon *et al.* are described above. Gordon *et al.* do not teach retroviral expression vectors or eukaryotic host cells.

Temin *et al.* teach a recombinant retrovirus vector, which allows the transfection and expression of genes in eukaryotic host cells (abstract, column 1, line 60-column 2, line 58 and claims).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the fusion protein comprising a collagen-binding domain {von Willebrand Factor (vWF)} and an epithelial cell proliferation-modulation domain (TGF-β1) of Gordon *et al.* by expressing the nucleic acid encoding the fusion in a retroviral vector and eukaryotic host cells, as suggested by Temin *et al.* with a reasonable expectation of success. The motivation and expected success is provided by Temin *et al.* who teach that some genetically caused diseases may be curable by introducing foreign DNA into eukaryotic cells and allowing the foreign DNA to express a protein that the genetically defective cell cannot express. Temin *et al.* teach that the introduction of foreign DNA into eukaryotic cells can be done with retrovirus vectors.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or

discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 66-71 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, of prior **U.S. Patent No. 6,387,663 B1**. This is a double patenting rejection.

Claims 66-71 are directed to the same invention as that of claims 1-4 of commonly assigned **U.S. Patent No. 6,387,663 B1**. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Claims 72-79 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8, 11, of prior **U.S. Patent No. 6,955,898 B2**. This is a double patenting rejection.

Claims 72-79 are directed to the same invention as that of claims 1-8 and 11 of commonly assigned **U.S. Patent No. 6,955,898 B2**. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
12/10/05

JOSEPH MURPHY
PATENT EXAMINER